REMARKS/ARGUMENTS

Amendment to the Claims

Claims 1-15 and 17-21 are in the application. Claims 9 is amended. Claim 16 is canceled.

Claims 9 is amended to correct grammar.

No new claims fees are believed due, and all claim amendments are fully supported by the specification as originally filed.

Objection to the Claims

Applicants thank the Examiner for pointing out the correction required to Claim 9. Applicants have amended Claim 9 as suggested by the Examiner.

Rejections under 35 USC §103(a)

A. Claims 1, 2, 10, 11 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miskinyar (US 5527287) in view of Woehr et al. (US 20030144627)

The rejection is substantially identical to the prior rejection, with the addition of the following statement: "Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to inject at a volumetric flow rate of about 0.5 μL/s to about 20 μL/s, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233.

Applicants traverse, and incorporate by reference the arguments made in the last response mailed April 27, 2009.

Applicants have asserted in the last response mailed April 27, 2009 that Miskinyar fails to disclose a manually-powered injection device, as such would be understood by a person of ordinary skill given the broadest reasonable interpretation of Applicants' specification. The Examiner has not been given patentable weight to the recitation of "manually-powered" in the preamble (see rejection item 15). Applicants note that the body the claim 1 requires that the needle is configured for axial movement manually between a first position wherein the injection end is within the housing and a second position intramuscular insertion of the injection end. It

would appear that the Examiner has not have considered this feature of the claim, which embodies in the claim the "manually-powered" aspect of the invention described in paragraph [0065]. The preamble recitation of "manually-powered" in the preamble should also be considered for its patentable weight because it provides basis for the axial movement manually of the needle.

Miskinyar also does not describe or overcome the problem addressed by the "manually-powered" feature of the invention, described in paragraph [0075]. Quite the contrary, the device of Miskinyar requires a pre-charged syringe that uses an actuator button to release the pre-charged needle for injection.

Applicants also traverse the rejection's characterization of the prior art of Miskinyar as being capable of administering a painless injection "especially to a patient or injection location with a high pain threshold". The Applicants describe at paragraph [0084] that typically a painless needle insertion can be achieved using an injection needle having an outer diameter of about 0.36 mm (28 gauge needle) and less, and for small children, infants and patients having more sensitive skin, an outer diameter of about 0.30 mm (30 gauge needle) and less (31 gauge to 33 gauge). A person of ordinary skill in the art would not understand that extreme exceptions (individuals with high pain thresholds and injection areas experiencing low pain) qualify the entire range of needle sizes disclosed in Miskinyar as being capable of administering a painless needle insertion.

Applicants also traverse the rejection's characterization of the prior art of Miskinyar as being capable of "semi-permanent attachment" (rejection item 16). The Examiner construes semi-permanent attachment as encompassing "any way in which the apparatus could be made to stay in place at the injection site". Such construction is unreasonably overbroad, since the claim itself requires that the housing have a base for semi-permanent attachment to the skin, such that the semi-permanent attachment to the skin is through the base. A construction of "any apparatus with a needle, if inserted at an injection site, is technically semi-permanently attached to the skin," is technically outside the broadest reasonable interpretation of Applicants' claims.

Applicants also traverse the rejection's characterization of any reasonable construction of the combination of Woehr et al and Miskinyar (rejection item 17). Woehr et al appears to disclose the "push" and "pull" strengths standards for needle hubs of variously sized needles. It

should be noted that these strength standards pertain to the *attachment of the base of the needle to the needle hub*, and *not* to the force for inserting or retracting the needle through the skin itself. While Woehr et al discloses a broad range of needle sizes, Woehr et al makes no teaching or suggestion to the person of ordinary skill in the art to select only the smaller sizes in the range described in Applicants' invention. That knowledge, with all due respect, in not disclosed or suggested in either Woehr et al or Miskinyar et al. To consider otherwise attributes a teaching to Woehr et al and Miskinyar et al which they do not make.

Regarding claim 21, the rejection fails to show in the prior art an injection rate in the claimed range, and the prior art of record does not appear to recognize the result achieved. Paragraph [0086] discloses that for a typical medicament volume of about 0.5 ml to about 1.0 ml, a substantially painless to completely painless injection can be achieved over an injection period of from about 1 minute to about 10 minutes, more typically from about 3 minutes to about 5 minutes. The references fail to disclose the claimed range, and fail to recognize the importance thereof in preventing or minimizing pain resulting from the rate of liquid injection.

B. Claims 3-8, 12-15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miskinyar in view of Woehr et al., and further in view of McWethy et al. (US 7004929).

The rejection is substantially identical to the prior rejection.

Applicants traverse, and incorporate by reference the arguments made in the last response mailed April 27, 2009.

Applicants traverse the rejection's characterization of the prior art of Miskinyar as disclosing a means for retracting the injection needle from its second extended position to a third position wherein the injection end is within the housing (rejection item 19). The rejection makes an apparently baseless assertion that "the behavior of spring 102 (of Miskinyar) during injection does not preclude its ability to function as a retraction mechanism after injection has been completed". Miskinyar (Figures 8 and 9, and column 5 lines 18-32) disclose that actuator spring 128 forces the ampule chamber 96 outwardly to its extended position, which inherently would require that the force of actuator sprint 128 overwhelms the misnomered "retraction" spring 102, which "is *designed to be less than* the force required for slidably advancing the piston 100 in the ampule chamber 96, thereby *ensuring* that the medication is not prematurely ejected" (emphasis added). A person of ordinary skill would conclude that spring 102 cannot retract the injection

needle from its second extended position to a third position wherein the injection end is within the housing, as the claims expressly require.

Applicants have already traversed the rejection's characterization of "manually-powered", discussed above (rejection item 20).

Applicants also traverse the rejection as based on a characterization of the prior art made by merely reciting the elements and features of Applicants' claim (see Rejection item 21). A *prima facie* rejection requires that the examiner make a factual inquiry that includes ascertaining the differences between the claimed invention and the prior art. A rejection that fails to identify the specific features of the prior art, but merely labels them using the terminology of Applicants' claims, cannot "identify the differences between the claimed invention and the prior art", as is required of a *prima facie* rejection.

Applicants have already traversed the rejection's characterization of the prior art of McWethy as disclosing a needle insertion securement (see Rejection item 22).

C. Claims 9 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miskinyar in view of Woehr et al., and further in view of Flaherty (US 6749587).

Applicants traverse, and incorporate by reference the arguments made in the last response mailed April 27, 2009.

D. Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miskinyar in view of Woehr et al. and McWethy, and further in view of Landau (US 6264629).

Applicants traverse, and incorporate by reference the arguments made in the last response mailed April 27, 2009.

Prosecution of Related Patent Applications

Applicants wish to bring to the Examiner's attention the examination status of related patent applications commonly assigned to the assignee of the instant application:

i) **US Appln. 10/605,187** (Attorney docket CHM-005M), presently allowed, with respect to claim 21 of the instant application.

ii) **US Appln. 10/597,997** (Attorney docket CHM-022M), presently under final rejection, with respect to claims 9 and 20 of the instant application.

Conclusion

Applicants believe a complete response to the office action has been provided, and that the remarks provided overcome the obviousness rejections against the present claims.. Applicants request a prompt Advisory Action, and a notice of allowance as to all claims.

Respectfully submitted,

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